

EXHIBIT 5

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS
CASE NO. 16-cv-12182-FDS

-----X
THE UNITED STATES OF AMERICA,
et al. ex rel. JULIE LONG,
Plaintiffs,
-v-
JANSSEN BIOTECH, INC.,
Defendant.
-----X.

Remote videotaped deposition of
CHRISTOPHER ZALESKY
Friday, December 8, 2023
8:48 a.m. Eastern Time

Reported by:
Gail L. Inghram Verbano,
Registered Diplomat Reporter,
Certified Realtime Reporter,
Certified Shorthand Reporter-CA (No. 8635)
HUDSON COURT REPORTING & VIDEO (800) 310-1769

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1 APPEARANCES:

2
3 For the Plaintiff/Relator:
4 (Via Zoom Videoconferencing)

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8 Whereupon, the remote videotaped
9 deposition of CHRISTOPHER ZALESKY was held via
10 Zoom videoconferencing on Friday, December 8,
11 2023, beginning at approximately 8:48 a.m.,
12 Eastern Time, the proceedings being recorded
13 stenographically by Gail Verbano, Registered
14 Diplomat Reporter, Certified Realtime
15 Reporter, Certified Shorthand Reporter, and
16 transcribed under her direction, there being
17 present:
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1 APPEARANCES (Continued):
2 (Present with the witness)

3
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18
19 ALSO PRESENT:
20 (Via Zoom Videoconferencing)
21 KEVIN MARTH, Videographer
22
23
24
25

Pages 1 to 4

1 A. Anything that ultimately would
2 have been shared with customers and they were
3 starting with FDA's advertising and promotion
4 had to go through PRC; but there might have
5 been other components of the initiative, some
6 behaviors or practices or structures or
7 services that weren't sort of customer-facing
8 but were also carefully evaluated but never
9 actually went to PRC; essentially thoughts and
10 ideas as opposed to pieces of paper.

11 Q. And I don't want to know what was
12 said, but did the legal member of the PRC ever
13 have any input as to promotional strategies?

14 ATTORNEY RAOFIELD: Objection to
15 form.

16 BY ATTORNEY RAZAVI:

17 Q. Just yes or no for now.

18 A. Yes.

19 Q. Okay. Pause for your attorney on
20 this.

21 What would the scope of the legal
22 member's input as to promotional strategies --
23 well, strike that.

24 Would the scope of the legal
25 member of the PRC's input as to promotional

1 included to a broad portfolio of things,
2 including things like, you know,
3 anticompetition law, patient safety, products
4 liability. You know, there could have been
5 manufacturing or other issues as well in there.

6 But they are also, sort of from
7 a legal standpoint, responsible for making
8 sure we were complying with the company's
9 healthcare compliance policies in addition to
10 me, you know. So we were both looking at
11 proposed activities, a compliance arena
12 together; but they were looking in sort of
13 more legally-focused, and my focus was whether
14 or not the behaviors and practices comply with
15 company's policies.

16 BY ATTORNEY RAZAVI:

17 Q. So did the legal member of the
18 PRC ever have any input as to antikickback or
19 false claim act issues as it pertained to
20 promotional strategies?

21 ATTORNEY RAOFIELD: Objection to
22 form. I think we're -- I think we're getting
23 into privileged areas. I'm trying to
24 understand that question.

25 Yeah, I mean, I have to instruct

1 strategies be any different than any other
2 member of the PRC? Just yes or no.

3 ATTORNEY RAOFIELD: Objection to
4 form of the question.

5 THE WITNESS: Yes.

6 BY ATTORNEY RAZAVI:

7 Q. Okay. Wait for your attorney:
8 How so? How would it have been different?

9 ATTORNEY RAOFIELD: I need a
10 minute here.

11 So I think -- I think that if
12 you're able, you can answer that question at a
13 general level without getting into particular
14 conversations with counsel because the
15 question is going towards, I think, as I
16 understand it, a functional level. But if you
17 have any trouble with that -- answering that,
18 we can take a break and confer to protect
19 privilege.

20 But if you think you're able to,
21 you can answer.

22 THE WITNESS: Sure. And I think
23 we've already discussed some of this before.
24 So, I mean, the lawyer's job was what the
25 lawyer determined their job should be, and it

1 the witness not to answer on the basis of
2 privilege.

3 ATTORNEY RAZAVI: Obviously, we
4 respectfully disagree but it is what it is.
5 Okay.

6 BY ATTORNEY RAZAVI:

7 Q. For example, the medical affairs
8 representative on the PRC, I suspect, typically
9 did not have input as to antikickback or false
10 claim issues as it pertains to promotional
11 strategies; is that fair?

12 ATTORNEY RAOFIELD: Objection to
13 the form of the question.

14 THE WITNESS: That wasn't their
15 area of responsibility.

16 BY ATTORNEY RAZAVI:

17 Q. Okay. So the question I have is,
18 would the legal member of the PRC, would that
19 have been within their area of responsibility?

20 ATTORNEY RAOFIELD: Okay. We're
21 back to the same -- let me see.

22 ATTORNEY RAZAVI: Are you
23 instructing him not to answer?

24 ATTORNEY RAOFIELD: I'm
25 reading -- reading the question.

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1 ATTORNEY RAZAVI: I'm focusing
2 more on roles rather than actual advice given
3 for this line of questioning at the moment.
4 ATTORNEY RAOFIELD: Yeah, well,
5 I'm confused because I thought he had already
6 answered that question, and then you are coming
7 back to it. So I'm trying to make sure there's
8 nothing else going on here.
9 I think he had already answered
10 that as a yes-or-no question, so I'll let him
11 answer that yes or no.
12 ATTORNEY RAZAVI: Do you want me
13 to reask the question?
14 ATTORNEY RAOFIELD: Yes, please.
15 BY ATTORNEY RAZAVI:
16 Q. Would -- would having input as to
17 antikickback or false claims issues as it
18 pertains to promotional strategies fall within
19 the responsibility of the legal member of the
20 PRC?
21 ATTORNEY RAOFIELD: Objection to
22 the form of the question.
23 THE WITNESS: And I can answer?
24 ATTORNEY RAOFIELD: Yes. Yes or
25 no.

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1 THE WITNESS: Yes.
2 ATTORNEY RAOFIELD: And I think
3 we've got -- we've got to -- you can do what
4 you got to do for it but I'm trying to let you
5 ask as much as I can but I think we're at the
6 limit.
7 ATTORNEY RAZAVI: I get it. I
8 get it. Again, respectfully we disagree but I
9 hear you.
10 BY ATTORNEY RAZAVI:
11 Q. So what I'm trying to unpack is,
12 throughout this morning we've been talking
13 about how -- was the regulatory's -- regulatory
14 member's responsibility to evaluate compliance
15 issues as related to advertising and
16 promotional issues, and the legal member
17 focused more on, you know, product liability,
18 manufacturing issues, antitrust issues.
19 Is that a correct summation so
20 far, before I go further?
21 ATTORNEY RAOFIELD: Objection to
22 the form of the question. I think the prior
23 testimony speaks for itself.
24 BY ATTORNEY RAZAVI:
25 Q. You can -- you can answer.

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1 THE WITNESS: Can I answer?
2 ATTORNEY RAOFIELD: Yeah.
3 THE WITNESS: We've talked --
4 again, we've talked about sort of the evolution
5 of the copy review process. And at the
6 beginning it was largely focused on -- at least
7 the regulatory part was largely focused on FDA
8 advertising and promotion. And as time went
9 by, certainly after the company was acquired
10 and J&J started putting in place its healthcare
11 compliance policies, the compliance with the --
12 with those policies also fell into the
13 regulatory bucket as well.
14 BY ATTORNEY RAZAVI:
15 Q. Okay. So let me just stick with
16 the 2003 time period.
17 In 2003 was the PRC's regulatory
18 member's responsibility to evaluate compliance
19 issues as it related to advertising and
20 promotional issues, as opposed to the legal
21 member, who was focused more on product
22 liability, antitrust, and manufacturing issues?
23 Is that a generally fair statement?
24 A. No.
25 Q. Tell me -- tell me where I'm

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1 wrong.
2 A. You're sort of trying to -- it's
3 hard to tease out a line between where the
4 regulatory role ends and where the legal area
5 begins, because the regulations are all based
6 on the law. And so if regulatory affairs
7 professionals were responsible to understand
8 what the law is and where it came from, but our
9 job isn't to interpret or apply or advise on
10 the law; it's to read the regulations, to
11 understand the company's policies in
12 implementing those regulations, and provide
13 guidance.
14 As it happens, the lawyers have
15 responsibilities, not only the ones that you
16 mentioned like products liability, patient
17 safety, and all that, but they also have legal
18 responsibilities when it comes to FDA as well
19 as fraud and abuse rules as well. So the
20 categorical buckets overlap, but the actual
21 functions are different.
22 ATTORNEY RAZAVI: Gotcha.
23 ATTORNEY RAOFIELD: I have to
24 make a statement on the record at this point.
25 Yeah, I think we've been very

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1 clear, including with filings to the Court,
 2 that Janssen is not waiving attorney-client
 3 privilege. We're not asserting advice of
 4 counsel. We're in a deposition where I can't
 5 control the questions that you choose to ask
 6 the witness. And you're asking a lot of
 7 questions that get into areas -- and I'm
 8 trying to draw the line at the appropriate
 9 point to protect privilege consistent with our
 10 determined effort not to waive privilege or
 11 assert an advice of counsel defense.
 12 I'm not asking the questions.
 13 I'm not choosing to bring any of this into
 14 issue. You are. But I'm doing my best to
 15 draw the line here to be consistent with all
 16 of that.
 17 ATTORNEY RAZAVI: And I
 18 appreciate that. Again, respectfully I do
 19 disagree. I think we do need to get into these
 20 line of questioning to address Janssen's good
 21 faith basis defense, but that's for another day
 22 for us to fight.
 23 But, again, we'll make sure to
 24 give time for you to object and instruct when
 25 you feel appropriate.

1 BY ATTORNEY RAZAVI:
 2 Q. So let me give you more of a
 3 specific example, which we'll actually go into
 4 in a minute.
 5 So a simple antikickback issue.
 6 You're familiar with the concept of not having
 7 independent value associated with the marketing
 8 strategy regarding a pharmaceutical that's
 9 presented to a medical provider; correct?
 10 General framework.
 11 ATTORNEY RAOFIELD: Give me one
 12 second.
 13 Object to the form of the
 14 question.
 15 THE WITNESS: Well, I -- I'm
 16 familiar with the term "independent value."
 17 BY ATTORNEY RAZAVI:
 18 Q. And you're aware that there's --
 19 well, okay, let's actually go into it, and then
 20 we'll tease it out a little bit more.
 21 ATTORNEY RAZAVI: All right.
 22 And, Jason, I'm not going to necessarily be
 23 attaching everything I show to him as an
 24 exhibit. If you want to later on, we'll
 25 allocate for that.

1 I'm going to show you what's
 2 Bates-stamped JANSSEN-37-844 -- let me attach
 3 it here.
 4 ATTORNEY RAOFIELD: If it's a
 5 production document, I'm not sure why you
 6 wouldn't mark it as an exhibit.
 7 ATTORNEY RAZAVI: I just don't
 8 like to have a zillion exhibits going back and
 9 forth that may or may not be relevant, just my
 10 personal style.
 11 ATTORNEY RAOFIELD: We'll see
 12 what it is. I think to have an accurate
 13 record, if, you know -- if it was a pleading or
 14 something -- anyway, you go ahead, and I'll let
 15 you know if I see an issue.
 16 ATTORNEY RAZAVI: No, I hear you.
 17 Okay.
 18 BY ATTORNEY RAZAVI:
 19 Q. So let me show you this document;
 20 all right. This Centocor Healthcare Compliance
 21 Resource Guide, the first page is Bates-stamped
 22 JANSSEN-37-845. Does this look at all familiar
 23 to you?
 24 A. I don't remember it.
 25 Q. I understand, you know, it's 100

1 some pages, don't ask that you remember it.
 2 Do you recall Centocor having an
 3 HCC Resource Guide when you were there?
 4 A. We have different names for
 5 different things at different times, and this
 6 could well be one of those things.
 7 Q. Okay. To the extent that
 8 Centocor did have an HCC Compliance Resource
 9 Guide while you were there, would you have
 10 played any role in its creation or drafting or
 11 editing, or anything like that?
 12 ATTORNEY RAOFIELD: I'm going to
 13 object. If -- I don't think it's possible --
 14 especially with how small this is too. But,
 15 like, I don't think it's possible for the
 16 witness to answer questions based on, like, one
 17 page of a however -- we can't even see how many
 18 pages this document is.
 19 ATTORNEY RAZAVI: So let me --
 20 let's -- let's take it away from this document.
 21 BY ATTORNEY RAZAVI:
 22 Q. Did you play any role in the
 23 creation of any healthcare compliance resource
 24 guide up through 2004 at either Centocor or
 25 Janssen?

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1 And let me ask you --
 2 ATTORNEY RAOFIELD: And, again,
 3 Poorad, you're just asking about -- I'm trying
 4 to let you ask your questions without asserting
 5 privilege. But you're -- you're currently
 6 talking about sort of functional roles on the
 7 PRC; you're not talking about, you know, legal
 8 advice provided by lawyers to the company?
 9 ATTORNEY RAZAVI: Correct. I'm
 10 not asking about any drug or anything in
 11 particular. You know, for example, the
 12 question was, which member of the PRC was in
 13 charge of identifying the physical side effects
 14 of a drug, I assume the answer would have been
 15 the medical end, not the lawyer. So what I'm
 16 trying to figure out here is whose role -- who
 17 would have had the -- let me ask it this way.
 18 Who would have had the greater
 19 role in evaluating whether a service had
 20 substantial independent value for antikickback
 21 purposes on the PRC from '99 through 2004?
 22 Would it have been the regulatory person or
 23 the legal person? Or was it 50/50?
 24 ATTORNEY RAOFIELD: Objection to
 25 the form of the question. Again, I think

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1 you've covered this extensively. I'm just very
 2 worried because we keep going back over and
 3 over things involving lawyers in a case where
 4 relator has announced an intention to argue
 5 that we've waived privilege, so I'm being as
 6 cautious as I possibly can. And I'm concerned
 7 that you keep coming back to something that you
 8 asked him about for, like, an hour.
 9 To the extent you can answer,
 10 you can answer.
 11 ATTORNEY RAZAVI: Do you want me
 12 to ask the question again, Mr. Zalesky?
 13 THE WITNESS: Sure.
 14 BY ATTORNEY RAZAVI:
 15 Q. So who would have had the greater
 16 role in evaluating whether a service had a
 17 substantial independent value for antikickback
 18 purposes on the PRC committee from 1999 through
 19 2004? Would it have been the regulatory member
 20 or the legal member, or is it more of a 50/50
 21 split?
 22 ATTORNEY RAOFIELD: Objection to
 23 the form of the question.
 24 THE WITNESS: So the evaluation
 25 is essentially what's the proposed practice.

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1 The question is, does that comply with the
 2 company's policies? And that was part of my
 3 job to do that evaluation; but the lawyers also
 4 looked at those factors, and it's hard to
 5 imagine what the range of potential practices
 6 might have been.
 7 But there could have been, you
 8 know, proposals that were made that might have
 9 been compliant with the company's policies but
 10 they might have raised other, you know, fraud
 11 and abuse questions. So it's -- it's part --
 12 so we both looked at it. It was both
 13 consideration, and I wouldn't say that it
 14 was -- you know, I wouldn't assign a
 15 proportion to it. We both -- it was part of
 16 both of our jobs.
 17 BY ATTORNEY RAZAVI:
 18 Q. And would -- would legal have led
 19 an evaluation of whether a service had
 20 substantial independent value when reviewing a
 21 strategy outside of the PRC committee paradigm?
 22 ATTORNEY RAOFIELD: Objection. I
 23 don't -- I can't -- can't possibly imagine a
 24 way in which there's an answer to that question
 25 that doesn't come as a result of conversations

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1 with counsel. So --
 2 ATTORNEY RAZAVI: So it -- sorry,
 3 sorry, finish your thing and --
 4 ATTORNEY RAOFIELD: No, if you
 5 want to -- if you want to try to change it, but
 6 as -- like I've said, we're not putting any of
 7 this into evidence ourselves. You're asking
 8 these question. I can't stop you from asking
 9 questions but I have to draw the privilege
 10 line.
 11 And it's gone on for so long,
 12 but if you want to try to rephrase it.
 13 ATTORNEY RAZAVI: Yeah, so the
 14 question I'm asking -- and, Mr. Zalesky, this
 15 is for Jason. The question I'm asking is
 16 geared still again towards function rather than
 17 any actual advice given; and so that's all I'm
 18 trying to find out is the responsibility
 19 delegation.
 20 So let me ask it with that
 21 framework. And, Jason, if you've got to tell
 22 him not to answer, you've got to tell him not
 23 to answer. I think it's appropriate, but let
 24 me see.
 25 ///

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1 BY ATTORNEY RAZAVI:

2 Q. So would the legal department
3 from '99 through 2004 have conducted an
4 evaluation of whether services had substantial
5 independent value when reviewing a strategy
6 outside of the PRC committee's system or
7 methodology?

8 ATTORNEY RAOFIELD: Objection to
9 form. Instruct the witness not to answer on
10 the basis of privilege, given that there's no
11 way he can possibly know, other than through
12 conversations with counsel, what the legal
13 department was doing or not doing outside of
14 the PRC process.

15 ATTORNEY RAZAVI: Respectfully we
16 disagree but it is what it is. Okay.

17 BY ATTORNEY RAZAVI:

18 Q. Have you heard of the term
19 "Patient access" in any way, shape, or form
20 while working at the company throughout your
21 career?

22 A. I've heard that expression. I
23 mean, I'm not sure what the context was.

24 Q. Is it something you've heard, you
25 know, just in passing once or twice; or is it

1 something that you believe was something that
2 came up with some frequency?

3 A. Well, I mean, I don't think we've
4 covered this, but Remicade is not a pill. It's
5 not an injection. It's an infused product.
6 And it was, if not the first of its type, close
7 to the first of its type, and perhaps the first
8 infused product of its type.

9 And so the doctors who deliver
10 the product to patients have to think about how
11 they were going to either provide access to
12 patients to get that infusion or to provide
13 access to patients by providing that infusion
14 themselves. So in that context, patient access
15 comes up, like, how are patients going to be
16 able to receive the drug?

17 Q. And is this what you -- the
18 answer you just gave, is this something you
19 actually encountered and dealt with while
20 employed with J&J or Janssen or Centocor?

21 A. What the -- the question of
22 making sure that patients have access to the
23 drug came up, sure.

24 Q. Okay. Specifically to Remicade?

25 A. Well, I think it's generally true

1 of all drugs. I mean, there's supply chain
2 issues where -- that affect patient access, and
3 there's other issues that affect patient
4 access. So it's not unique to Remicade.

5 Q. Yes, sorry, let me -- let me
6 rephrase it.

7 Did you play a role in evaluating
8 the appropriateness of using patient access as
9 a justification to deliver services to medical
10 practitioners for Remicade or Simponi Aria?

11 ATTORNEY RAOFIELD: Objection to
12 the form of the question.

13 THE WITNESS: So any sort of
14 program like that, if I understand what you're
15 referring to, and I'm not sure I do -- any
16 program like that would have gone through the
17 company's copy review process to be evaluated
18 for both the, you know, FDA aspects of it,
19 healthcare compliance aspects of it, and the
20 privacy aspects of it.

21 So in my capacity as sitting on
22 the copy review, I'm -- I'm sure I reviewed
23 some of those materials.

24 BY ATTORNEY RAZAVI:

25 Q. And to the extent that did pass

1 your way, that would have ended by
2 2004/2005-ish; is that right?

3 A. It would have been before then,
4 because that's -- by 2004 is when I had gone to
5 corporate; so it would have been prior to 2004.

6 Q. Gotcha. Okay.

7 Is there any OIG guidance or
8 policy or even a Janssen -- or Johnson &
9 Johnson or Centocor or Janssen policy that you
10 can guide us to that indicates that patient
11 access is a justification for providing
12 healthcare providers with services that had
13 independent value?

14 ATTORNEY RAOFIELD: Objection to
15 the form of the question.

16 THE WITNESS: That was a long
17 list of places to look. There -- there was J&J
18 compliance policy guidance on -- and I think we
19 saw a slide on this a -- "Product-Related Items
20 and Services" or something like that. So
21 that -- my recollection was that was the name
22 of the guidance document that probably would
23 have governed this sort of thing. But, again,
24 I'm not sure exactly what you're talking about.

25 ///